

Food and Drug Administration, HHS

§ 520.1720e

not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications*. For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000061 and 010797 for use of product described in paragraph (a)(1) of this section.

(2) No. 064847 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Do not use in horses intended for human consumption. Federal law restricts this

drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007]

§ 520.1720d Phenylbutazone gel.

(a) *Specifications*. Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system of horses.

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 520.1720e Phenylbutazone powder.

(a) *Specifications*—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 027053 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.